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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/825,183

04/16/2004

Antoine De Gaulle

P25150

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08/21/2006

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EXAMINER

LAU, HOI CHING

ART UNIT

PAPER NUMBER

2612

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/825,183

Applicant(s)

DE GAULLE ET AL.

Examiner

Hoi C. Lau

Art Unit

2612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,7,9,13,15-19 and 24-28 is/are rejected.
- 7) ☒ Claim(s) 2,4-6,8,10-12,14 and 20-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1- 28 have been examined.

Response to Amendment

2. The Office acknowledges the change made to the claim by the applicant. The objections of claims 1 and 3 have been withdrawn.

3. Examiner admits on page 5 of Office action filed on March 21st, 2006 where said claims 11 and 21 are being rejected base on rejection of claim 4 is left by mistake. However, according to Office Action Summary and page 7 of Office action filed on March 21st, 2006, it clearly stated all claims 4, 11 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Therefore this action is made final.

Response to Arguments

4. Applicant's arguments filed March 20, 2006 have been fully considered but they are not persuasive. The followings are applicant's arguments:
 - a. Levin fails to teach the features of defining a maximum allowed time; requalification and dequalification, wherein requalification of the blood bag when both the maximum time dT and the expiration date have not expired.
 - b. Reber does not teach indicating an alert when the cumulative time outside the storage place exceeds the threshold.

c. Levin fails to disclose basing the status (requalified or dequalified), or the indication of that status, on the expiration of either or both of the maximum time dT and/or the expiration date.

The followings are response to applicant's arguments:

1. Regarding argument (a) and (c), Levin teaches blood bag is being check and monitor through the central computer via RFID wherein the requalification and dequalification methods of blood bags are done manually by remove and dispose of product based upon the expiration date which allowing the blood bag to be requalified (restore to cabinet) when the expiration date have not expired and for the blood bag to be de-qualified (remove and dispose) when the expiration date have expired (page 8, paragraph 72, 80). Further, status indication also provides by computer system through database in response with the RFID of blood bag.

The secondary reference, Reber, teaches a restore method in respect with monitoring for a discard condition of food item if the predetermine time duration (maximum time allowed) of expose outside is exceeded (column 3, lines 37 and column 4, lines 5-10 and lines 22-68 and column 5, lines 1-48). The motivation of the combination would be under relevant background wherein both blood bag and food item are considering as perishable products which require to store under certain temperature to maintain its shelf-life and freshness. In addition, the maximum time allowed monitoring method would be an addition element with the Levin's requalification and dequalification method in respect with expiration date for quality analysis.

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2. Regarding arguments (b), the limitation “cumulative time” of applicant’s argument is not being claim nor disclose in any part of the claims.

Drawings

5. The drawings are objected to because it does not clearly describe the claim invention by showing only block diagram and components need to be label instead of numeral. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3, 7, 9, 13, 15-18, 19 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin (U.S. 2002/0143320) in view of Reber et al. (U.S. 5,969,606).

Regarding **claim 1**, Levin teaches the blood bag having an electronic clip fixed thereto, the electronic chip having a loop antenna structured (figure 1) and arranged to communicate with an electronic communication device (440) and a simplified electronic communication device having a loop antenna connected to a programmable automation device (442) (figures 1, 1 and 8 and page 2, paragraphs 14, 16 and page 5, paragraphs 51, 52);

Wherein transmitting an expiration date, defined as starting from an initial time determined by donation in a parent blood bag, carried out in a blood transfusion unit, by using the electronic communication device which is combined with an agitating balance, the expiration date being stored in the electronic chip of the parent blood bag and then transferred to the electronic chip of a primary blood bag, then transferred to the electronic chips of secondary blood bags (page 7, paragraphs 66-70);

And allowing the blood bag to be re-qualified when the expiration date have not expired, and for the blood bag to be de-qualified when the expiration date have expired (page 8, paragraph 72, 80).

It fails to specific mention the determination of which a maximum allowed time ΔT for being kept outside a controlled-atmosphere enclosure is also defined for qualification.

However, Levin teaches a real-time inventory method for tracking the entering and transporting period between the blood bank and other facilities where route and destination are noted and recorded (page 7, paragraphs 66, 67, 69 and page 8, paragraphs 74-77).

Beber teaches a method of tracking food product include electronic clip to monitor for a discard condition of item if the predetermine time duration of expose outside is exceeded (column 3, lines 37 and column 4, lines 5-10 and lines 22-68 and column 5, lines 1-48).

It would have been obvious to one of ordinary skill in the art to combine the time threshold determination taught by Beber with the blood bag tracking system taught by Levin because any perishable product such as blood and food item requires to store under certain temperature to maintain the shelf-life and freshness in order to provide a safe blood and food product and their derivative. Furthermore, the combination would result in quality monitoring to decrease product waste.

As to **claim 3**, Levin teaches the tag tracking system is associated with the surgical implement in the operating room includes check-in and check-out time (paragraphs 26-32, 38 and 42) and the combination with Beber teaches the re-qualification method when taken out of a controlled-atmosphere enclosure, a re-qualification time then being stored in the electronic chip (see claim 1 for rejection).

It would have been obvious to one of ordinary skill in the art to associate the tag with blood bag when the blood bag is not used and not returned to the controlled-atmosphere enclosure to de-qualified because it would ensure the safety of blood product by maintain the product temperature.

As to **claim 7**, the combination meets the limitation of claims and show a total time for which the blood bag may be kept outside the controlled-atmosphere enclosure (see claim one for rejection).

It fails to clearly mention of allowing only one blood bag at a time to be outside.

It would have been obvious to one of ordinary skill in the art to allow only one bag to be outside the enclosure because it would reduce the waste of blood during operation or under a confusing and rushing environment.

Regarding **claim 9, 19, 26 and 27**, they correspond to claim 1 and they are therefore rejected for the similar reasons set forth in the rejection of claim 1.

As to **claim 11 and 21**, they correspond to claim 4 and they are therefore rejected for the similar reasons set forth in the rejection of claim 4.

As to **claim 13 and 24**, they correspond to claim 7 and they are therefore rejected for the similar reasons set forth in the rejection of claim 7.

As to **claim 15 and 28**, Levin show transferring the expiration date stored in the electronic chip of a parent blood bag to the electronic chip of a primary blood bag, and to the electronic chips of secondary blood bag (paragraphs 66-67).

As to **claim 16 and 17**, Levin teaches the use of blood bag, recordable medium (reader and network system), and controlled-atmosphere enclosure (storage cabinet) associate with the tracking system (figure 7 and see rejection of claim 1).

As to **claim 18**, the combination meets the limitation of claim except it fails to show a vehicle having a controlled-atmosphere enclosure structure and arranged to practice method of claim 9.

However, it would be obvious to one of ordinary skill in the art the system would implement a vehicle with a refrigerated enclosure as a transportation to transfer and distribute the blood bag for a long and extended traveling range and distance from one facility to another as illustrate in figure 7 because it would safe and reduce the labor cost and effectively transfer blood for necessary use.

As to **claim 25**, Levin teaches each compartment being equipped with a specialized electronic communication device, the compartmentalized controlled-atmosphere enclosure being managed by a programmable automation device (422) (figure 7, paragraphs 66-67, 72-75 and 80).

Allowable Subject Matter

7. Claim 2,4-6, 8, 10-12, 14 and 20-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

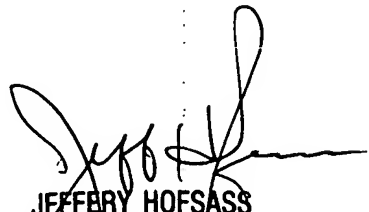
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hoi C. Lau whose telephone number is (571)272-8547. The examiner can normally be reached on M- F 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Hofsass can be reached on (571)272-2981. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hoi C. Lau
Art Unit 2612


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